history there is confirms the Agency's interpretation that evidence of intent should not be restricted to promotional claims.

Congress most directly addressed the issue during consideration of the 1976 Medical Device Amendments. In the House Report, the Committee on Energy and Commerce specifically considered whether a manufacturer could avoid having its product regulated as a medical device intended for human use by labeling and promoting the device as intended for animal use only. Contrary to the tobacco industry's position, the House Report concluded that FDA would not be bound by the manufacturer's promotional claims:

> This is not to say, however, that a manufacturer of a device that is banned by the Secretary [for human use] can escape the ban by labeling the device for veterinary use. *The Secretary may consider the ultimate destination of a product in determining whether or not it is for human use, just as he may consider actual use of a product in determining whether or not it is a device.*

Medical Device Amendments of 1976, H.R. Rep. No. 94-853, 94th Cong., 2d Sess. 14 (emphasis added), *reprinted in* An Analytical Legislative History of the Medical Device Amendments of 1976, appendix III. Congress' reasoning confirms the plain meaning of the statutory definitions of "drug" and "device." It shows that Congress plainly intended FDA to be able to look behind a manufacturer's promotional claims and to determine intent based on the actions of the manufacturer and the actual uses of the product.

The tobacco industry relies primarily on a passage from the 1935 Senate Report, which states that "the manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put." S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935), *reprinted in* 3 Legislative History 60, 663.

However, the first sentence of the paragraph from which the tobacco industry quotes states that "[t]he use to which the product is to be put will determine the category into which it will fall." *Id.* This quotation is consistent with the Agency's interpretation that consumer use can establish "intended use" independent of the manufacturer's claims.

Furthermore, the passage quoted by the tobacco industry is taken out of context, however. Congress was not addressing the issue of how to determine whether a product is intended to affect the structure or function of the body under the Act's drug definition, section 201(g)(1)(C). Rather, the issue being discussed was the circumstances under which the Agency must regulate a product both as a food and as a drug intended for use in the diagnosis or treatment of disease under section 201(g)(1)(B) of the Act. (By definition, a "food" cannot be regulated as a drug under section 201(g)(1)(C) of the Act.) In this context, the Senate Committee stated that a manufacturer could "escape" regulation of a product as a food by "representing the article fairly and unequivocally as a drug product." *Id.*

The Senate Committee did not say that promoting the article exclusively as a food could remove the article from the drug definition of section 201(g)(1)(B), however. To the contrary, the Committee stated that "[i]f it is to be *used* only as a food it will come within the definition of food and none other." *Id.* (emphasis added). Thus, this legislative history shows that a manufacturer's representations cannot force the Agency to regulate a product containing a drug as a food; rather, regulation as a food is compelled only if the sole *use* of the product is as a food. Accordingly, the legislative history on which the comments rely supports only the limited argument that a manufacturer's representations can ensure that a product *is* regulated as a drug. The passage does not support—and

indeed contradicts—the position that a manufacturer's representations can prevent regulation of a product as a drug.

The cigarette industry also cites the following language from the same Senate Committee report to support the view that a manufacturer's claims are the only relevant consideration in determining the intended use of a product:

> While soaps sold only for ordinary toilet or household use are specifically exempted from the definition of cosmetic and will not be subject to the definition of drug, soaps for which claims concerning disease are made or which are sold as pharmacopoeial articles will come within the definition of drug and will thus be subject to regulation.

Id. at 3-4, *reprinted in* 3 Legislative History 662-663. This language, however, merely states the unarguable and long-settled principle that a drug claim can bring any article (regardless of the article's composition or effects) within the Agency's jurisdiction. *See, e.g., United States v. An Article . . . "Sudden Change,"* 409 F.2d 734, 739 (2d Cir. 1969). This is not the issue before the Agency in this case.

The passages of the legislative history quoted by the tobacco industry, "when read fairly and in light of their true context, . . . cannot be said to demonstrate a [true] Congressional desire." *Jewell Ridge Coal Corp. v. United Mine Workers*, 325 U.S. 161, 168-169 (1945). The most that can reasonably be said in support of the tobacco industry's view is that the legislative history is sparse and ambiguous—a circumstance that calls for deference to the Agency's interpretation of the plain language of the statute. As the Supreme Court recently held, "[w]hen we find . . . that the legislative history is ambiguous and unenlightening on the matters with respect to which the regulations deal,

we customarily defer to the expertise of the agency." *Rust v. Sullivan*, 500 U.S. 173, 186 (1991).

2. The cigarette manufacturers contend that reading a foreseeability standard into "intended use" is unworkable because it would convert "every foreseeable off-label use" of a drug or a device into an "intended use" attributable to the manufacturer. In support of this contention, the cigarette industry points to what has become known as FDA's "practice of medicine" policy, under which the Agency recognizes that physicians may, if their medical judgment so dictates, prescribe (but not promote) an approved drug for an unapproved use without violating the Act. *See* 37 FR 16503 (Aug. 15, 1972).

The Agency disagrees with this comment. Fundamental differences distinguish off-label uses of approved drugs from cigarettes and smokeless tobacco. First, before a drug can have an off-label use, the drug must first have been regulated by FDA for an approved use. Unlike off-label uses of approved drugs, cigarettes and smokeless tobacco have not previously been regulated by FDA for approved uses.

Second, FDA's practice-of-medicine policy is based on FDA's long-standing policy of not interfering with the practice of medicine. Most off-label uses of prescription drugs are prescribed by a physician. FDA has made a policy judgment that, because of the involvement of a doctor, FDA will not generally interfere with these off-label uses. The policy considerations that underlie the practice-of-medicine policy are entirely missing in the case of cigarettes and smokeless tobacco.

In any event, under the practice-of-medicine policy, "[w]here the unapproved use of an approved new drug *becomes widespread or endangers the public health*, 'FDA will investigate and' *take whatever action is warranted to* protect *the public*." *See* 37 FR

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16504 (Aug. 15, 1972) (emphasis added). Thus, this policy recognizes that the Agency may assert jurisdiction over unapproved uses of drugs when they become "widespread" or endanger the public health—even in the absence of promotional claims by the manufacturer. This closely parallels the Agency's interpretation that it may assert jurisdiction over products when it becomes foreseeable that they will have drug effects upon, and be used for drug purposes by, a significant proportion of consumers.

3. The smokeless tobacco industry asserts that FDA's reliance on consumer use to confer drug or device status on an article is, in effect, an attempt to define drugs and devices in the same way that the Act defines foods. Under the Act, the term "food" means "articles used for food or drink for man or other animals." Section 201(f), 21 U.S.C. 321(f). The smokeless tobacco industry argues that if "drug" or "device" status can be inferred whenever a product is used in a certain way, then the statutory intent requirement becomes mere surplusage.

The Agency disagrees. To determine that a product is a drug or device, FDA is required to show that the "intended use" by a manufacturer for a product is as a drug or device. This statutory intent requirement can be satisfied based on "use" alone only where the use is sufficiently widespread. Evidence of "use" can also provide a relevant source of information in combination with other types of evidence. *See ASH*, 655 F.2d at 239-240.

4. The tobacco industry characterizes evidence from the statements, research, and actions of manufacturers as "classic examples of subjective intent, i.e., motives that are not publicly expressed," and states that the regulations allow the Agency to prove the "intended use" of a product based only on evidence of "objective intent." Thus, the tobacco industry argues that the Agency must disregard the extensive evidence in the

administrative record indicating that the manufacturers actually intend that cigarettes and smokeless tobacco have, and will be used for, pharmacological effects.

FDA concludes that evidence of the statements, research, and actions of tobacco manufacturers is relevant to determine the "intended use" of a product. The tobacco industry's position that evidence bearing on their actual intentions is not relevant conflicts with the plain language of the Act. The tobacco industry's position also conflicts with the regulations defining "intended uses."[1133]

Moreover, acceptance of the tobacco industry's argument that FDA must disregard evidence of the manufacturers' statements, research, and actions would frustrate the public health purposes of the Act. FDA does not test products before they are marketed, nor does the Agency have the right to examine the manufacturer's testing data before a new product is marketed unless the manufacturer submits an application for approval of the drug or device prior to marketing. Consequently, neither FDA nor the consumer is ordinarily in a position to know whether a new product that the manufacturer claims is *not* a drug or device in fact has pharmacological effects on consumers. In contrast, the manufacturer, through its research and product development activities, knows the effects of the product on consumers and knows how the manufacturer's formulation and design choices are likely to influence the uses to which the product will be put. To interpret "intended use" to exclude evidence of what the manufacturer has

[1133] The phrase "subjective intent" is ambiguous. To the extent that "subjective intent" is understood to refer to the actual intent of the manufacturer, the Agency may consider objective evidence of this "subjective" or actual intent in determining the manufacturers' intent. Alternatively, to the extent that "subjective intent" is understood to refer to the intent the manufacturer claims to have, *see, e.g., NNFA v. Mathews*, 557 F.2d at 334; *see also Latex Surgeons' Gloves*, 799 F. Supp. at 1295, "the FDA is not bound by the manufacturer's subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence." *Mathews*, 557 F.2d at 334.

designed its product to do, and anticipates its product will be used for, would thus permit, and even encourage, unscrupulous manufacturers to conceal their knowledge of the products' significant pharmacological effects so as to avoid application of the Act. This would directly undercut the public health purposes of the Act.

Accordingly, FDA concludes that objective evidence of tobacco manufacturers' actual intent from their statements, research, and actions is relevant to establishing the intended use of cigarettes and smokeless tobacco.[1134]

b. Comments on Administrative Precedents

The tobacco industry and an individual commented on the administrative precedents. The comments make two main arguments. First, the comments argue that FDA did not rely solely on known pharmacological effects or consumer use to establish the intended use of the products discussed in the examples. Second, the comments argue that the examples cited did not represent authoritative interpretations of the law. The comments address each of the examples in some detail.

FDA's response is set forth below. In brief, the cited examples are valid precedents in which FDA found intended drug or device use based on factors other than express claims (i.e., known effects or consumer use). Moreover, contrary to the tobacco

[1134] Even if the Agency accepted the tobacco industry's argument that manufacturers' statements, research, and actions cannot be considered to prove the manufacturers' intent, it does not follow that such evidence is not *also* relevant for other purposes. For example, much of this evidence corroborates the scientific evidence showing that tobacco products have significant pharmacological effects and are used by consumers to obtain these effects. The Agency may properly use the evidence of the statements, research, and actions to establish these facts. Furthermore, the Agency may properly use the evidence from the statements, research, and actions of the manufacturers to rebut assertions by the manufacturers that they do not intend to make products that have and are used for pharmacological effects.

industry's assertions, the examples support the position that nicotine in tobacco products is a drug.

1. The tobacco industry asserts that FDA's administrative precedents are not analogous to tobacco products because the precedents in fact relied on implied promotional claims in establishing intended use. For instance, the comments assert that the mere listing of the word "hormone" on a skin cream was viewed by FDA as an implied drug claim and argue that "the Agency asserted that any statement in the labeling of these products that hormones are present is an implied drug claim . . . Thus, the determining factor is *claims*—implied or express—made *in marketing* the product."[1135]

These comments on the basis for FDA's finding of intended use are incorrect. First, in most of the administrative precedents, no implied claims were involved. For instance, there were no express or implied claims involved in the Agency's assertion of jurisdiction over "khat." Similarly, in most of the imitation cocaine precedents, the manufacturers were deliberately trying to avoid FDA jurisdiction by advertising their products for nondrug uses.[1136] The novelty condom precedents discussed in the Jurisdictional Analysis, in which the condoms were labeled as novelty and not functional condoms, also did not involve any promotional claims. *See* 60 FR 41530 (Aug. 11, 1995).

[1135] Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. II, at 91 (emphasis in original). *See* AR (Vol. 535 Ref. 96).

[1136] The Agency recognizes that in one imitation cocaine case, *United States v. Storage Spaces Designated Nos. "8": and "49,"* 777 F.2d 1363 (9th Cir. 1985), the reviewing court did find some evidence of promotional claims. Even in that case, however, "the items were called 'incense' and advertised as 'Not for drug use,'" and the court stated that "[s]elf-serving labels cannot be allowed to mask the vendor's true intent as indicated by the overall circumstances." *Id.* at 1366 n.5. In most of FDA's actions against imitation cocaine, the manufacturers' promotional materials were generally designed to disguise the actual intended use.

It is true that the listing of hormones on the label of skin creams can be considered an implied drug claim. However, this implied claim argument does not distinguish cigarettes and smokeless tobacco from the administrative precedents. If the mere listing of the drug ingredient "hormone" on a skin cream constitutes an implied drug claim, then similar implied drug claims are regularly made for tobacco products. Many cigarette advertisements list nicotine deliveries.[1137] Nicotine is a widely recognized drug with significant pharmacological effects. It is the active ingredient in several products regulated as drugs by FDA. Therefore, if the listing of hormones in skin creams can be considered an implied drug claim, the listing of nicotine in cigarette advertisements can also be considered an implied drug claim.

Moreover, in the case of hormone-containing skin creams, FDA independently relied upon the foreseeable drug effects of the creams as a basis for establishing intent. FDA took the position that the inclusion of pharmacologically active levels of hormones in the skin creams was a sufficient basis for regulating the products as drugs. *See* 58 FR 47611, 47613 (Sep. 9, 1993).

2. The tobacco industry also alleges that, in some of the examples, intended drug use had previously been established because the product contained an active drug ingredient. For instance, the tobacco industry argues that the imitation cocaine cases involved bulk prescription drug ingredients (e.g., lidocaine and ephedrine) that were diverted for use in the imitation cocaine products. The comments' point seems to be that once intended drug use is established for one use of a drug, FDA can establish the same

[1137] American Society of Addiction Medicine, Comment (Dec. 29, 1995), appendix 6. *See* AR (Vol. 528 Ref. 97).

drug intent with respect to manufacturers of other products containing the drug as an ingredient.

The Agency agrees that the presence of a known drug ingredient can be substantial evidence of an intent to affect the structure and function of the body. However, the Agency disagrees that this point distinguishes any of the administrative precedents from tobacco products. To the contrary, cigarettes and smokeless tobacco contain a known drug, nicotine, that has addictive and other significant pharmacological effects. It is the active drug ingredient in several products regulated as drugs by FDA, including nicotine patches, nicotine gum, and nicotine nasal sprays. The comments' position leads to the conclusion that products containing nicotine, including cigarettes and smokeless tobacco, are also drugs.

3. The tobacco industry argues that the administrative precedents are not authoritative interpretations of the law. Instead, the comments assert, the examples consist of unchallenged assertions, preliminary pronouncements in certain rulemaking proceedings, and judicial default and consent decrees, rather than specific actions and litigated cases. One comment minimizes some of the examples by stating that preliminary views and opinions are not binding on FDA itself. Another comment asserts that the "Agency position" in the case of one example, vaginal products, was really that of an independent advisory committee, and, in any case, the Agency itself later rejected the position. Still another comment contends that the Agency cited a relatively small number of examples, implicitly suggesting that this limited the precedential value of the collection of examples.